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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,406	05/29/2001	John Clark Lagarias	407T-907720US	7073
22798	7590	04/06/2004	EXAMINER	
QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501			PAK, YONG D	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/870,406	Applicant(s) LAGARIAS ET AL.	
	Examiner Yong D Pak	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-38 and 80-82 is/are pending in the application.
 4a) Of the above claim(s) 33-36 is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 37,38 and 80-82 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/21/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on January 20, 2004, amending claims 33, 35 and 37, canceling claims 1-32 and 39-79 and adding claims 80-82, has been entered.

Claims 33-38 and 80-82 are pending.

Election/Restrictions

Applicants elected Group III, with a further election of DNA encoding the HY2 bilin reductase shown in Figure 3.

Claims 33-34 were incorrectly withdrawn in the previous action.

However, newly amended claims 33-36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 33-36 are drawn to a consensus sequence as illustrated in Figure 5 or Figure 10. The elected claims 37-38 and 80-82 are drawn to DNA encoding a HY2 bilin reductase as shown in Figure 3 (SEQ ID NO:33). Further, claims 33-36 are not drawn to a generic family of HY2 bilin reductase (which would have been examined), but are drawn to a consensus sequence of many bilin reductases. The consensus sequence of such a broad family of bilin reductases is a sequence that reflects the most common choice of base or amino acid at each position. Therefore, the consensus sequence is patentably distinct from the bilin reductase of SEQ ID NO:33 because the two have different structure and some parts of the consensus sequence structure may be different from the structure of SEQ ID NO:33. Also a HY2 bilin reductase of SEQ ID NO:33 and the consensus sequence of bilin reductases have different substrate specificity and the consensus sequence may be inactive.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 33-36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on July 27, 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claims 80-81 are objected for being drawn to non-elected products, DNA encoding a bilin reductase other than the HY2 bilin reductase shown in Figure 3 and for being dependent on a non-elected claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 80-81 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 80-81 are drawn to a nucleic acid molecule encoding a HY2 bilin reductase. Therefore, these claims are drawn to a genus of HY2 bilin reductase, with any structure and from any source. Art teach that HY2 bilin reductase is not well known in the art, but the specification only teaches one representative species, SEQ ID NO:33, from *Arabidopsis thaliana*. One representative species is not enough to describe the whole genus and there is no evidence on the record of the relationship between the structure of an *Arabidopsis thaliana* HY2 bilin reductase and the structure of a HY2 bilin reductase from another source. Therefore, the specification fails to describe other representative species of the genus of HY2 bilin reductase.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 35-38.

Claims 80-81 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid molecule encoding the HY2 bilin reductase of SEQ ID NO: 33, does not reasonably provide enablement for a nucleic acid molecule encoding a HY2 bilin reductase not homologous to SEQ ID NO:33. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Despite knowledge in the art for the isolation of polynucleotides, the specification fails to provide guidance regarding how to isolate other polynucleotides encoding HY2 bilin reductase whose sequence is not homologous to SEQ ID NO:33. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

The predictability as to the level of conservation between the disclosed sequences and those of other carbonyl reductase is extremely complex. While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

Therefore, one of ordinary skill would require guidance in order to make nucleic acid molecule encoding a HY2 bilin reductase not homologous to SEQ ID NO:33 in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-38 and 80-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37-38 and 82 are drawn to a nucleic acid that hybridizes with SEQ ID NO:33. This is confusing because SEQ ID NO:33 is an amino acid sequence.

Claim 35 is drawn to a consensus sequence. Claims 80-81, which depend from claim 35, are confusing because claims 80-81 are drawn to a HY2 bilin reductase of SEQ ID NO:33 and not a consensus sequence of bilin reductases.

In claims 80-82, the mere recitation of the name "hvrccr" or "atrccr" is insufficient to convey with clarity that which applicant sees as the invention.

Response to Arguments

The objection of the specification has been withdrawn in light of the amendment.

The objection of the drawing has been withdrawn in light of the amendment.

The rejection under 101 has been withdrawn in light of the amendment.

The rejection under 102(a) has been withdrawn.

The rejection under 103(a) has been withdrawn.

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

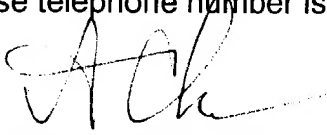
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong D. Pak
Patent Examiner


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNICAL STAFF